SENATE BILL No. 347

DIGEST OF INTRODUCED BILL

Citations Affected: IC 5-10-8-15; IC 12-15-5-9; IC 27-8-25; IC 27-13-7-20.

Synopsis: Coverage for care related to clinical trials for cancer. Requires coverage for certain services related to clinical trials for cancer under a state employee health plan, the state Medicaid program, a policy of accident and sickness insurance, and a health maintenance organization contract.

Effective: July 1, 2009.

Gard

January 8, 2009, read first time and referred to Committee on Health and Provider Services.





First Regular Session 116th General Assembly (2009)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in this style type, and deletions will appear in this style type.

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in this style type. Also, the word NEW will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in this style type or this style type reconciles conflicts between statutes enacted by the 2008 Regular Session of the General Assembly.

SENATE BILL No. 347

A BILL FOR AN ACT to amend the Indiana Code concerning insurance.

Be it enacted by the General Assembly of the State of Indiana:

SECTION 1. IC 5-10-8-15 IS ADDED TO THE INDIANA CODE	
AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY	V
1, 2009]: Sec. 15. (a) As used in this section, "care method" means	
the use of a particular drug or device in a particular manner.	
(b) As used in this section, "clinical trial" means a Phase I, II,	

- III, or IV research study: (1) that is conducted:
 - (A) using a particular care method to prevent, diagnose, or treat a cancer for which:
 - (i) there is no clearly superior, noninvestigational alternative care method; and
 - (ii) available clinical or preclinical data provide a reasonable basis from which to believe that the care method used in the research study is at least as effective as any noninvestigational alternative care method;
 - (B) in a facility where personnel providing the care method to be followed in the research study have:



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1	(i) received training in providing the care method;	
2	(ii) expertise in providing the type of care required for	
3	the research study; and	
4	(iii) experience providing the type of care required for	
5	the research study to a sufficient volume of patients to	
6	maintain expertise; and	
7	(C) to scientifically determine the best care method to	
8	prevent, diagnose, or treat the cancer; and	
9	(2) that is:	
10	(A) exempt from the federal Food and Drug	
11	Administration's investigational new drug or device	
12	application requirement as provided under 21 CFR 312 or	
13	21 CFR 812; or	
14	(B) approved or funded by one (1) of the following:	
15	(i) A National Institutes of Health institute.	
16	(ii) A cooperative group of research facilities that has an	
17	established peer review program that is approved by a	
18	National Institutes of Health institute or center.	
19	(iii) The federal Food and Drug Administration.	
20	(iv) The United States Department of Veterans Affairs.	
21	(v) The United States Department of Defense.	
22	(vi) The institutional review board of an institution	
23	located in Indiana that has a multiple project assurance	
24	contract approved by the National Institutes of Health	
25	Office for Protection from Research Risks as provided in	
26	45 CFR 46.103.	
27	(vii) A research entity that meets eligibility criteria for a	
28	support grant from a National Institutes of Health	V
29	center.	
30	(c) As used in this section, "covered individual" means an	
31	individual entitled to coverage under a state employee health plan.	
32	(d) As used in this section, "routine care cost" means the cost of	
33	medically necessary services related to the care method that is	
34	under evaluation in a clinical trial. The term does not include the	
35	following:	
36	(1) The drug or device that is under evaluation in a clinical	
37	trial.	
38	(2) Items or services that are:	
39	(A) provided solely for data collection and analysis and not	
40	in the direct clinical management of an individual enrolled	
41	in a clinical trial;	
42	(B) customarily provided at no cost by a research sponsor	



1	to an individual enrolled in a clinical trial; or	
2	(C) provided solely to determine eligibility of an individual	
3	for participation in a clinical trial.	
4	(e) As used in this section, "state employee health plan" means	
5	one (1) of the following:	
6	(1) A self insurance program established under section 7(b) of	
7	this chapter to provide group health coverage.	
8	(2) A contract with a prepaid health care delivery plan that is	
9	entered into or renewed under section 7(c) of this chapter.	
0	(f) A state employee health plan that provides coverage for basic	
1	health care services (as defined in IC 27-13-1-4) must provide	
2	coverage for routine care costs related to a clinical trial for a	
3	covered individual participating in the clinical trial.	
4	SECTION 2. IC 12-15-5-9 IS ADDED TO THE INDIANA CODE	
.5	AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY	
6	1, 2009]: Sec. 9. (a) As used in this section, "care method" means	
7	the use of a particular drug or device in a particular manner.	
8	(b) As used in this section, "clinical trial" means a Phase I, II,	
9	III, or IV research study:	
20	(1) that is conducted:	
21	(A) using a particular care method to prevent, diagnose, or	
22	treat a cancer for which:	
23	(i) there is no clearly superior, noninvestigational	
24	alternative care method; and	
25	(ii) available clinical or preclinical data provide a	
26	reasonable basis from which to believe that the care	
27	method used in the research study is at least as effective	
28	as any noninvestigational alternative care method;	V
29	(B) in a facility where personnel providing the care method	
0	to be followed in the research study have:	
31	(i) received training in providing the care method;	
32	(ii) expertise in providing the type of care required for	
3	the research study; and	
34	(iii) experience providing the type of care required for	
55	the research study to a sufficient volume of patients to	
66	maintain expertise; and	
57	(C) to scientifically determine the best care method to	
8	prevent, diagnose, or treat the cancer; and	
19	(2) that is:	
10	(A) exempt from the federal Food and Drug	
1	Administration's investigational new drug or device	
-2	application requirement as provided under 21 CFR 312 or	



1	21 CFR 812; or	
2	(B) approved or funded by one (1) of the following:	
3	(i) A National Institutes of Health institute.	
4	(ii) A cooperative group of research facilities that has an	
5	established peer review program that is approved by a	
6	National Institutes of Health institute or center.	
7	(iii) The federal Food and Drug Administration.	
8	(iv) The United States Department of Veterans Affairs.	
9	(v) The United States Department of Defense.	
10	(vi) The institutional review board of an institution	4
11	located in Indiana that has a multiple project assurance	
12	contract approved by the National Institutes of Health	•
13	Office for Protection from Research Risks as provided in	
14	45 CFR 46.103.	
15	(vii) A research entity that meets eligibility criteria for a	
16	support grant from a National Institutes of Health	4
17	center.	
18	(c) As used in this section, "routine care cost" means the cost of	
19	medically necessary services related to the care method that is	
20	under evaluation in a clinical trial. The term does not include the	
21	following:	
22	(1) The drug or device that is under evaluation in a clinical	
23	trial.	
24	(2) Items or services that are:	_
25	(A) provided solely for data collection and analysis and not	
26	in the direct clinical management of an individual enrolled	
27	in a clinical trial;	
28	(B) customarily provided at no cost by a research sponsor	
29	to an individual enrolled in a clinical trial; or	
30	(C) provided solely to determine eligibility of an individual	
31	for participation in a clinical trial.	
32	(d) The Medicaid program must provide coverage for routine	
33	care costs related to a clinical trial for a recipient participating in	
34	the clinical trial.	
35	(e) The office shall apply to amend the state Medicaid plan if the	
36	office determines that an amendment is necessary to carry out this	
37	section.	
38	SECTION 3. IC 27-8-25 IS ADDED TO THE INDIANA CODE AS	
39	A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1,	
40	2009]:	
41	Chapter 25. Coverage for Care Related to Clinical Trials	
42	Sec. 1. As used in this chapter, "care method" means the use of	



1	a particular drug or device in a particular manner.	
2	Sec. 2. As used in this chapter, "clinical trial" means a Phase I,	
3	II, III, or IV research study:	
4	(1) that is conducted:	
5	(A) using a particular care method to prevent, diagnose, or	
6	treat a cancer for which:	
7	(i) there is no clearly superior, noninvestigational	
8	alternative care method; and	
9	(ii) available clinical or preclinical data provide a	
10	reasonable basis from which to believe that the care	4
11	method used in the research study is at least as effective	
12	as any noninvestigational alternative care method;	
13	(B) in a facility where personnel providing the care method	
14	to be followed in the research study have:	
15	(i) received training in providing the care method;	
16	(ii) expertise in providing the type of care required for	4
17	the research study; and	
18	(iii) experience providing the type of care required for	
19	the research study to a sufficient volume of patients to	
20	maintain expertise; and	
21	(C) to scientifically determine the best care method to	_
22	prevent, diagnose, or treat the cancer; and	
23	(2) that is:	
24	(A) exempt from the federal Food and Drug	
25	Administration's investigational new drug or device	
26	application requirement as provided under 21 CFR 312 or	
27	21 CFR 812; or	
28	(B) approved or funded by one (1) of the following:	
29	(i) A National Institutes of Health institute.	
30	(ii) A cooperative group of research facilities that has an	
31	established peer review program that is approved by a	
32	National Institutes of Health institute or center.	
33	(iii) The federal Food and Drug Administration.	
34	(iv) The United States Department of Veterans Affairs.	
35	(v) The United States Department of Defense.	
36	(vi) The institutional review board of an institution	
37	located in Indiana that has a multiple project assurance	
38	contract approved by the National Institutes of Health	
39	Office for Protection from Research Risks as provided in	
40	45 CFR 46.103.	
41	(vii) A research entity that meets eligibility criteria for a	
42	support grant from a National Institutes of Health	



1	center.	
2	Sec. 3. As used in this chapter, "covered individual" means an	
3	individual entitled to coverage under a policy of accident and	
4	sickness insurance.	
5	Sec. 4. As used in this chapter, "policy of accident and sickness	
6	insurance" has the meaning set forth in IC 27-8-5-1. The term does	
7	not include the following:	
8	(1) Accident only, credit, dental, vision, Medicare, Medicare	
9	supplement, long term care, or disability income insurance.	
10	(2) Coverage issued as a supplement to liability insurance.	
11	(3) Automobile medical payment insurance.	
12	(4) A specified disease policy.	
13	(5) A limited benefit health insurance policy.	
14	(6) A short term insurance plan that:	
15	(A) may not be renewed; and	
16	(B) has a duration of not more than six (6) months.	
17	(7) A policy that provides a stipulated daily, weekly, or	
18	monthly payment to an insured during hospital confinement,	
19	without regard to the actual expense of the confinement.	
20	(8) Worker's compensation or similar insurance.	
21	(9) A student health insurance policy.	
22	Sec. 5. As used in this chapter, "routine care cost" means the	
23	cost of medically necessary services related to the care method that	
24	is under evaluation in a clinical trial. The term does not include the	
25	following:	
26	(1) The drug or device that is under evaluation in a clinical	
27	trial.	
28	(2) Items or services that are:	
29	(A) provided solely for data collection and analysis and not	
30	in the direct clinical management of an individual enrolled	
31	in a clinical trial;	
32	(B) customarily provided at no cost by a research sponsor	
33	to an individual enrolled in a clinical trial; or	
34	(C) provided solely to determine eligibility of an individual	
35	for participation in a clinical trial.	
36	Sec. 6. A policy of accident and sickness insurance must provide	
37	coverage for routine care costs related to a clinical trial for a	
38	covered individual participating in the clinical trial.	
39	SECTION 4. IC 27-13-7-20 IS ADDED TO THE INDIANA CODE	
40	AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY	
41 42	1, 2009]: Sec. 20. (a) As used in this section, "care method" means	
41	the lise of a narticular drug or device in a narticular manner	



1	(b) As used in this section, "clinical trial" means a Phase I, II,	
2	III, or IV research study:	
3	(1) that is conducted:	
4	(A) using a particular care method to prevent, diagnose, or	
5	treat a cancer for which:	
6	(i) there is no clearly superior, noninvestigational	
7	alternative care method; and	
8	(ii) available clinical or preclinical data provide a	
9	reasonable basis from which to believe that the care	
10	method used in the research study is at least as effective	
11	as any noninvestigational alternative care method;	
12	(B) in a facility where personnel providing the care method	
13	to be followed in the research study have:	
14	(i) received training in providing the care method;	
15	(ii) expertise in providing the type of care required for	
16	the research study; and	
17	(iii) experience providing the type of care required for	
18	the research study to a sufficient volume of patients to	
19	maintain expertise; and	
20	(C) to scientifically determine the best care method to	
21	prevent, diagnose, or treat the cancer; and	
22	(2) that is:	
23	(A) exempt from the federal Food and Drug	
24	Administration's investigational new drug or device	
25	application requirement as provided under 21 CFR 312 or	
26	21 CFR 812; or	
27	(B) approved or funded by one (1) of the following:	
28	(i) A National Institutes of Health institute.	
29	(ii) A cooperative group of research facilities that has an	
30	established peer review program that is approved by a	
31	National Institutes of Health institute or center.	
32	(iii) The federal Food and Drug Administration.	
33	(iv) The United States Department of Veterans Affairs.	
34	(v) The United States Department of Defense.	
35	(vi) The institutional review board of an institution	
36	located in Indiana that has a multiple project assurance	
37	contract approved by the National Institutes of Health	
38	Office for Protection from Research Risks as provided in	
39	45 CFR 46.103.	
40	(vii) A research entity that meets eligibility criteria for a	
41 42	support grant from a National Institutes of Health	
12	center.	



1	(c) As used in this section, "routine care cost" means the cost of	
2	medically necessary services related to the care method that is	
3	under evaluation in a clinical trial. The term does not include the	
4	following:	
5	(1) The drug or device that is under evaluation in a clinical	
6	trial.	
7	(2) Items or services that are:	
8	(A) provided solely for data collection and analysis and not	
9	in the direct clinical management of an individual enrolled	
10	in a clinical trial;	
11	(B) customarily provided at no cost by a research sponsor	
12	to an individual enrolled in a clinical trial; or	
13	(C) provided solely to determine eligibility of an individual	
14	for participation in a clinical trial.	
15	(d) An individual contract or a group contract that provides	
16	coverage for basic health care services must provide coverage for	
17	routine care costs related to a clinical trial for an enrollee	U
18	participating in the clinical trial.	
19	SECTION 5. [EFFECTIVE JULY 1, 2009] (a) IC 5-10-8-15, as	
20	added by this act, applies to a state employee health plan that is	
21	established, entered into, issued, delivered, amended, or renewed	
22	after June 30, 2009.	
23	(b) IC 12-15-5-9, as added by this act, applies to a Medicaid risk	
24	based managed care contract that is entered into, delivered,	-
25	amended, or renewed after June 30, 2009.	
26	(c) IC 27-8-25, as added by this act, applies to a policy of	
27	accident and sickness insurance that is issued, delivered, amended,	
28	or renewed after June 30, 2009.	V
29	(d) IC 27-13-7-20, as added by this act, applies to an individual	
30	contract or a group contract that is entered into, delivered,	

amended, or renewed after June 30, 2009.

